IN THE TITLE

Please amend the title of the application as follows:

A Medical Device Containing Light-Protected Therapeutic Agent And a Method For Fabricating ~~Thereof~~ The Same

IN THE SPECIFICATION

Please amend the Specification as follows:

Please amend the paragraph beginning on page 4, line 15 and ending on page 4, line 23, as follows:

References do teach compositions utilizing light-protective coatings for variety of application. For instance, U.S. Patent No. 5,900,425 to Kanikanti[[,]] *et*[[.]] *al.* discloses pharmaceutical preparations having controlled release of the active compound. These preparations are typically administered orally. If the active compound is light-sensitive (Kanikanti[[,]] *et*[[.]] *al.* disclose nifedipine and nimodipine), the controlled-release tablets are provided with a light-protective coating in order to preserve the light-sensitive medicine from degradation.

Please amend the paragraph beginning on page 5, line 1 and ending on page 5, line 12, as follows:

As an example, Kanikanti[[,]] *et*[[.]] *al.* recommend spraying a water-based suspension of a film former, PEG (plasticizer), titanium dioxide and iron oxide (the light-scattering and absorbing pigments), followed by drying in hot air. Obviously, Kanikanti[[,]] *et*[[.]] *al.* use TiO_2 and Fe_2O_3 as light-protective compounds. However, Kanikanti[[,]] *et*[[.]] *al.* deal exclusively with tablets for oral administration. This reference does not describe nor suggest using light-protective compounds on stents. The difference in applications is quite substantial. In fact, a light protective coating for an oral tablet is fundamentally different than a light protective coating for an implantable device.

Please amend the paragraph beginning on page 5, line 14 and ending on page 6, line 4, as follows:

Using materials such as Fe_2O_3 to protect against light may be acceptable in the light protective coating for an oral tablet, but is not an acceptable method for the stent coatings because the stent coatings must be extremely inert and must not interfere with the body's inflammatory response in any way. Some experts have theorized that the etiology of restenosis is caused by inflammatory response. Materials ingested orally and which are subsequently excreted can be much more toxic than a material that is implanted in the tissues. In addition, the method described by Kanikanti[[,]] *et*[[.]] *al.* suggest using hot air to dry the light protective compound. In many cases the drug may be heat sensitive and cannot tolerate drying conditions at high temperatures. Moreover, for the tablets described by Kanikanti[[,]] *et*[[.]] *al.* there is no issue of post-processing raised by the inventors.

Please amend the paragraph beginning on page 6, line 6 and ending on page 6, line 14, as follows:

Clearly, the only protection from light that the tablets require in Kanikanti[[,]] *et*[[.]] *al.* is during storage. This protection can be easily achieved in a variety of ways, for instance, by using dark-glass tablets containers. Therefore, using the light protective layer containing titanium and iron oxides is truly optional. These alternative approaches cannot be used for stent coatings since the drug needs the most protection from light during the manufacturing process and post-processing when degradation is most likely to occur.

Please amend the paragraph beginning on page 6, line 16 and ending on page 7, line 2, as follows:

In another reference, U.S. Patent No. 5,314,741 to Roberts[[,]] *et*[[.]] *al.*, a polymeric article (a rubber article) is disclosed which is coated with a thin layer of a coating resistant to light and other elements (i.e., oxygen or ozone). Roberts[[,]] *et*[[.]] *al.* apply the light-protective coating on a polymeric substrate requiring protection. This substrate is rubber or a similar

vulcanized diene-derived elastomer. It is well known to those skilled in the art that such elastomers are highly vulnerable to UV radiation and oxidants and degrade easily unless special steps are taken to protect them.

Please amend the paragraph beginning on page 7, line 4 and ending on page 7, line 10, as follows:

Yet another patent, U.S. Patent No. 5,756,793 to Valet[[,]] *et*[[.]] *al.* describes a method of protecting surfaces of wood against damage by light and a protective coating for wood. Surfaces of wood which are exposed to intense sunlight are damaged primarily by the UV component of sunlight. The polymeric constituents of the wood are degraded as a consequence, leading to a roughening and discoloration of the surface.

Please amend the paragraph beginning on page 7, line 12 and ending on page 7, line 18, as follows:

The usual method of protecting wood against damage by light without giving up the visual image of the wood surface <u>is</u> to use a colorless polymer coating containing a light stabilizer, in particular a UV absorber. Valet[[,]] *et*[[.]] *al.* teach the use of a derivative of benzophenone as an UV absorber. Such compounds display a distinct stabilizer action against the effect of light, when applied in a coating composition.

Please amend the paragraph beginning on page 7, line 20 and ending on page 7, line 24, as follows:

Both Roberts[[,]] *et*[[.]] *al.* and Valet[[,]] *et*[[.]] *al.*, however, disclose only compositions where it is the outer surface of the substrate, be it rubber or wood, that is light-protected. These references do not teach the protection of the internal layers of the composition nor the protection of any light vulnerable fillers.

Please amend the paragraph beginning on page 9, line 5 and ending on page 9, line 8, as follows:

In one embodiment of this invention, the light- and/or UV-radiation protective compound is added to the topcoat polymer layer ~~and so-filled topcoat polymer layer is applied on top of the drug-polymer layer, instead of the pure topcoat polymer layer~~.

Please amend the paragraph beginning on page 9, line 15 and ending on page 9, line 18, as follows:

In yet another embodiment, the light- and/or UV-radiation protective compound is added directly to the drug-polymer layer. This embodiment can be also combined with the other two embodiments discussed above.

Please amend the paragraph beginning on page 10, line 1 and ending on page 10, line 6, as follows:

According to one aspect of this invention, a coating for a medical device[[s]] is provided, the coating having increased light resistance, the coating comprising a [[drug-]] polymer layer containing a drug ~~included into the drug-polymer layer~~, and a light- and/or UV-protective compound incorporated into the coating.

Please amend the paragraph beginning on page 10, line 8 and ending on page 10, line 13, as follows:

According to another aspect of this invention, a coating for a medical device[[s]] is provided, the coating having increased light resistance properties, the coating comprising a [[drug-]] polymer layer containing a drug ~~incorporated into the drug-polymer layer~~, and a topcoat

~~polymer~~ layer disposed over the drug-polymer layer, where a light- and/or UV-protective compound ~~dispersed~~ is included ~~within~~ in the topcoat layer.

Please amend the paragraph beginning on page 10, line 15 and ending on page 10, line 20, as follows:

According to yet another aspect of this invention, a coating for a medical device[[s]] is provided, the coating having increased light resistance properties, ~~and including~~ the coating comprising a [[drug-]]polymer layer containing a drug, ~~and~~ a topcoat layer disposed over the drug-polymer layer, ~~where~~ a film-forming ~~polymer~~ layer disposed ~~upon~~ over the topcoat layer, and [[the]] a light- and/or UV-protective compound ~~is dispersed~~ included in the film-forming ~~polymer~~ layer.

Please amend the paragraph beginning on page 10, line 22 and ending on page 11, line 2, as follows:

According to another aspect of this invention, a coating for a medical device[[s]] is provided, the coating having increased light resistance properties, the coating ~~and including~~ comprising a [[drug-]]polymer layer containing a drug, ~~where~~ and a light- and/or UV-protective compound ~~is dispersed within~~ included in the drug-polymer layer.

Please amend the paragraph beginning on page 11, line 4 and ending on page 11, line 10, as follows:

According to yet another aspect of this invention, a method for fabricating a medical article is provided, the method comprising ~~providing a medical device, applying~~ forming a coating ~~composition~~ onto [[the]] a medical device, wherein the coating ~~composition has increased light resistance, such increased light resistance provided by a light- and/or UV-protective compound incorporated into the~~

~~coating composition~~ comprises a polymer layer containing a drug, a topcoat layer disposed over the drug-polymer layer, and a light- and/or UV-protective compound included in the topcoat layer.

Please amend the paragraph beginning on page 17, line 4 and ending on page 17, line 12, as follows:

The light- and/or UV-radiation protective compound should be biocompatible and inert to the drug of the drug-polymer layer 3. Optionally, the compound may also have a therapeutic effect such as reducing platelet adhesion and fibrinogen binding. In addition to a colorant, other light- and/or UV-radiation protective compounds can be selected by those ~~ordinarily~~ skilled in the art, taking into account the functions and the amount of the drug, as well as the above-mentioned requirements of UV- and light-protection, biocompatibility and inertness.

Please amend the paragraph beginning on page 20, line 8 and ending on page 20, line 14, as follows:

Any of the ~~Either~~ embodiments shown by FIGs. 2A, 2B or 2C can be used with any kind of the primer polymer layer 2, which would be otherwise usable, according to the criteria known to those having ordinary skill in the art. The thickness of the primer polymer layer 2 is not affected by the use of a protective layer of this invention and the method of application of the primer layer 2 remains the same.